

**REMARKS**

This amendment is in response to the Official Action mailed on January 3, 2008. The period for filing a response having ended on April 3, 2008, Applicants submit herewith a petition for a two-month extension of time to reset the deadline for responding up to and including June 3, 2008.

Claims 2 and 5 have been amended; claims 26-38 and 39-50<sup>1</sup> have been withdrawn from consideration; new claims 51-53 have been added; and claim 1 was previously canceled. No new matter has been introduced by these amendments or claims. (See, e.g., p.12 1.25 to p. 13.1.15) Accordingly, independent claim 53, as well as independent claim 2 and corresponding dependent claims 3-25 and 51-53, are pending and presented for the Examiner's consideration in view of the following remarks.

**I. 35 U.S.C. § 112 REJECTIONS**

The Examiner has rejected claim 5 under 35 U.S.C. § 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants have amended the claim to recite that "one of the at least two or more test zones is a general chemistry reagent zone" and the "general chemistry reagent zone further comprises" an indicator. Applicants respectfully submit that the claim amendment overcomes the Examiner's rejection.

**II. 35 U.S.C. § 102 REJECTIONS**

The Examiner has rejected claims 2-25 under 35 U.S.C. § 102(b) as being anticipated by either U.S. Patent

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<sup>1</sup> By way of Amendment dated October 31, 2005, claims 39-50 are also pending in the application. However, such claims were not acknowledged in the Office Action dated August 10, 2007, requesting restriction of the claims or Applicant's response to same. Nonetheless, as it is assumed that restriction of such claims would have been required, claims 39-50 are therefore also withdrawn from consideration.

No. 5,559,041 to Kang et al. ("Kang") or U.S. Patent No. 5,707,818 to Chudzik et al. ("Chudzik"). In light of the presently amended claims, Applicants respectfully submit that the Examiner's rejection is overcome.

Applicants' presently claimed invention is directed to a dry reagent lateral flow strip assay device capable of detecting two or more analytes in a test sample. Specifically, Applicants have disclosed a transport matrix which is capable of distributing the sample in both a lateral direction and a transverse direction. Due to the layering of the sample treatment pad 240 with the transport matrix 242, which is in turn, overlapped by a metering or inverse spreading layer 246 and reagent layer 248, the fluid in the sample travels in a direction that extends upwardly or downwardly from the transport matrix. Thus, the transport matrix disperses the sample in a lateral direction in a two-dimensional plane, as well as in a transverse direction in a third dimensional plane "so as to direct [the] test sample to [the] two or more test zones." (Claim 2)

Kang is generally directed to an immunoassay device. The Examiner contends that Fig. 5 of Kang discloses the limitation of the presently claimed invention. Fig. 5 discloses a circular sample application zone 310 that is surrounded by six separate test zones (311a-311f) arranged radially. The Examiner appears to contend that a sample applied to the application zone 310 will travel in both a lateral and transverse or perpendicular direction. However, this direction is in the same two-dimensional plane, as opposed to traveling upward or downward in a transverse direction that is in a third-dimensional plane, such as disclosed by Applicants' claimed invention. Indeed, Kang fails to disclose a transport matrix, such as defined by Applicants' claimed invention. Moreover, Kang does not disclose that the sample travels "in a direction transverse to said lateral path . . . in a two-dimensional plane" and a "transverse path being in a

third-dimensional plane so as to direct [the] test sample to [the] two or more test zones." (Claim 2) Thus, Applicants respectfully submit that the Examiner's rejection based upon *Kang* is misplaced.

Similarly, *Chudzik* teaches that a sample in a detection device permits the sample to migrate in four directions along four strips, but in only one plane. (See col. 6 ll.58-60; FIG. 1) Each of the *Chudzik* zones (e.g., competition zone 22, retention zone 24 and readout zone 26) are positioned along each of the four strips, thereby obviating the need for the sample to travel in more than one plane. (See, e.g., col.5 ll.6-12; Fig. 1.) Thus, *Chudzik* fails to teach or suggest that the sample travels in both a lateral direction and a transverse direction, wherein the transverse direction is in a "third-dimensional plane so as to direct [the] test sample to said two or more test zones." (Claim 2) In this regard, *Chudzik* does not teach each of the claim limitations of the claimed invention.

Thus, for at least the foregoing reasons, *Kang* and/or *Chudzik* fail to teach or disclose the limitations of claims 2-25 and 51-53. Accordingly, Applicants respectfully submit that the Examiner's rejection is overcome and should be withdrawn.

### **III. 35 U.S.C. § 103 REJECTIONS**

The Examiner has also rejected dependent claims 14 and 18 under 35 U.S.C. § 103 as being obvious in view of *Kang* or *Chudzik*, in view of U.S. Patent No. 5,354,692 to Yang *et al.* ("*Yang*"). As previously discussed, *Kang* and/or *Chudzik* fail to disclose a "transport matrix" having a transverse path "being in a third dimensional plane so as to direct said test sample to . . . two or more test zones." Moreover, *Yang* fails to make up for this deficiency. Thus, for at least the foregoing reasons, it is believed that the Examiner's rejection based upon

these references is overcome. Accordingly, Applicants respectfully submit that the objections be withdrawn.

#### **IV. ALLOWABLE SUBJECT MATTER**

The Examiner has objected to claim 15 as being dependent upon a rejected base claim, but has indicated that the claim would be allowable if rewritten in independent form to include all of the limitations of the base claim and any intervening claims. In light of the amendments made to underlying claim 2, Applicants have rewritten prior claim 15 as new claim 53. Accordingly, it is respectfully submitted that the subject matter of claim 53 remains in condition for allowance.

#### **V. CONCLUSION**

As it is believed that all of the rejections set forth in the Official Action have been fully met, favorable reconsideration and allowance are earnestly solicited.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he telephone Applicants' attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

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